DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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L&K BIOMED Company, Limited
Ms. Yerim An
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil
Giheung-gu, Yongin-si
Gyeonggi-do, 446-916
Republic of Korea

July 29, 2015

Re: K143278
Trade/Device Name: LnK Posterior Cervical Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI
Dated: July 3, 2015
Received: July 6, 2015

Dear Ms. An:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143278

Device Name
LnK Posterior Cervical Fixation System

Indications for Use *(Describe)*
The LnK Posterior Cervical Fixation System is indicated for the following:
- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors

The implants are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following the reduction of fractures/dislocations or trauma in the spine.

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (CI-T3) spine.

The pedicle screws are limited to placement in T1-T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. Submitter: L&K BIOMED Co., Ltd.
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil
Giheung-gu, Yongin-si, Gyeonggi-do, 446-916,
Korea
Phone. 82-2-6717-1985
FAX .82-2-6717-1989

Contact Person: Yerim An

Date prepared: July 24, 2015

2. Device Identification

Trade Name	LnK Posterior Cervical Fixation System
Common Name	Spinal Fixation System
Product Code	KWP, MNI
Regulatory Class	II
Classification Name	21CFR888.3050 Spinal Interlaminal Fixation Orthosis 21CFR888.3070 Pedicle Screw Spinal System

3. Purpose of 510(k)

The L&K BIOMED Co.Ltd, here by submits this traditional 510(k): device modification to request a modification for our LnK Posterior Cervical Fixation System. The modifications are adding sizes and additional components.

4. Primary Predicate or legally marketed devices which are substantially equivalent

- Primary predicate: L&K BIOMED Co.,Ltd. / LnK Posterior Cervical Fixation System (K120879)

5. Description of the Device

The LnK Posterior Cervical Fixation System is a top-loading, multiple component, posterior (cervical-thoracic) spinal fixation system which consists of polyscrew, Reduction poly screw, partially screw, semi-reduction partially screw, straight rod, curved rod, transitional rod, set screw and hooks that can be used via an open surgical approach.

Materials:

Product	Material	Standard
Cervical Screw	Ti-6Al-4V ELI	ASTM F136
Rod	Ti-6Al-4V ELI	ASTM F136
	Cobalt-28Chromium-6Molybdenum-4Vanadium ELI	ASTM F1537

Hook	Ti-6Al-4V ELI	ASTM F136
Set Screw	Ti-6Al-4V ELI	ASTM F136

Any implant components other than the rods are not manufactured from cobalt chrome.

6. Indication for use

The LnK Posterior Cervical Fixation System is indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors

The implants are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following the reduction of fractures/dislocations or trauma in the spine.

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (CI-T3) spine.

The pedicle screws are limited to placement in T1-T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

7. Comparison of the technological characteristics of the subject and predicate devices

The LnK Posterior Cervical Fixation System is considered substantially equivalent to other legally marketed devices. They are similar in design, material, and indications for use.

No	Item	LnK Posterior Cervical Fixation System	LnK Posterior Cervical Fixation System (Primary Predicate)
1	Manufacturer	L&K BIOMED Co., Ltd.	L&K BIOMED Co., Ltd.
2	Material	Ti-6Al-4V ELI and CoCrMo alloy	Ti-6Al-4V ELI
3	510(K) number	K143278	K120879
4	Product Code	MNI, KWP	MNI, KWP
5	Class	ClassII	ClassII
6	Intended Use	The LnK Posterior Cervical Fixation System is indicated for the following: • DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)	The LnK Posterior Cervical Fixation System is indicated for the following: • DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)

		• Spondylolisthesis • Spinal stenosis • Fracture/dislocation • Failed previous fusion • Tumors The implants are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following the reduction of fractures/dislocations or trauma in the spine. Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (CI-T3) spine. The pedicle screws are limited to placement in T1-T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.	• Spondylolisthesis • Spinal stenosis • Fracture/dislocation • Failed previous fusion • Tumors The implants are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following the reduction of fractures/dislocations or trauma in the spine. Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (CI-T3) spine. The pedicle screws are limited to placement in T1-T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

8. Performance Data

Static compression bending testing was performed per ASTM F1717.

9. Conclusion

The LnK Posterior Cervical Fixation System is substantially equivalent to legally marketed predicates.